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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,621	09/15/2003	Michael S. Williams	9362-4	9764
20792	7590	10/13/2004		
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER LEVY, NEIL S	
			ART UNIT	PAPER NUMBER

1616

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/662,621

Applicant(s)

WILLIAMS ET AL.

Examiner

Neil Levy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/10/03 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Masking" is not clear as to intended limitation.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 11, 14-19, 22, 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Hile et al - 2000.

PLGA biocompatible intra luminal prostheses carrying toxic solvents, Methylene chloride, (p.178, 2.1) were subjected to super critical carbon dioxide (p. 180, col. 1) to extract the toxics. Process was under preserve, in an enclosed chamber, with temperature control (fig. 1. lowering density and toxic removal is shown at p. 181, col. 2).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greiner – EP 0405284 in view of Hile et al '2000 and Perman et al 5340614.

Greiner shows stents – shunts (col. 2, lines 33-45), of polypropylene, silicone polyurethane's impregnated with active by immersing in super critical carbon dioxide, while controlling temperature and pressure (p. 3, col. 1) then decreasing pressure (col. 3, p. 3). However, Greiner does not focus, although discloses (p.3, col. 3) – methylene chloride – alcohols on removable of toxics. Hile (above) shows that PLGA polymers, can be treated with super critical carbon dioxide to effect removal of solvents methylene chloride and other toxics, while Hile addresses – multiple use of polymer, for sustained release, including use as intra luminal prostheses (p. 177, 1.) with fibroblast growth fact or (bfgf). Stants are not specifically mentioned. Perman: the instant process is shown; solvent, (ethanol) tackifler and plasticizer removal by (col. 12) super critical carbon dioxide used with these toxics, (col. 9) to impregnate (col. 7, top) actives into biocompatible polymers, followed by reducing density (col. 10, top). However, stents are undisclosed, but the PLGA polymers are shown equivalently useable for impregnation of actives (col. 9, lines 35-50) inclusive of the Hile and Greiner polymers.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize stents, to use Greiner, modified with polymers of choice as shown equivalent by Perman, and not limited by solvent/ toxic residuals. Shown removable from PLGA polymers, also carrying bfgf, by Hile. Perman further shows use of co solvent (col. 5, lines 30-31) and also teaches biodegradable and non-erodible polymer (col. 6, lines 32-44). Masking of polymers, impregnation at low

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pressure (col. 10, bottom) may be necessary. Example 15 shows a polymeric coating can be applied polyurethane on polyamide or polyethylene.

All the critical elements of the instant are disclosed. The processes for preparation of ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each component in order to optimize the effect desired, depending upon the particular active to be administered, disease or condition of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected result that the use of the particular ingredients' or procedures provides any greater of different level of prior art expectation as claimed, the use of procedures and components for the functionality for which they are known to be used is not basis for patentability.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is (571) 272-0619. The examiner can normally be reached on Tuesday through Friday 7 AM to 5:30 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gray Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Levy/LR  
October 4, 2004

NEIL S. LEVY  
PRIMARY EXAMINER